

GENERIC LABEL

## PROPOSED GENERIC LABELING

**ACTIVE INGREDIENTS:** Each tablet contains either:

Amoxicillin.....	50 mg
Amoxicillin.....	100 mg
Amoxicillin.....	200mg
Amoxicillin.....	300mg
Amoxicillin.....	400mg
Amoxicillin.....	800mg

### INDICATIONS:

Dogs: Generic amoxicillin is indicated in the treatment of susceptible strains of the organisms causing the following infections:

Respiratory tract infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus*, *Streptococcus* spp. *E. coli* and *Proteus mirabilis*

Genitourinary tract infections (cystitis) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli* and *Proteus mirabilis*.

Bacterial dermatitis due to *Staphylococcus aureus*, *Streptococcus* spp., and *Proteus mirabilis*.

Soft tissue infections (abscesses, lacerations and wounds) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli* and *Proteus mirabilis*.

Cats: Generic amoxicillin is indicated in the treatment of susceptible strains of the organisms causing the following:

Upper respiratory tract infections due to *Staphylococcus aureus*, *Streptococcus* spp., and *E. coli*.

Genitourinary tract infections (cystitis) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli* and *Proteus mirabilis*.

Gastrointestinal tract infections due to *E. coli*.

Skin and soft tissue infections (abscesses, lacerations and wounds) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli* and *Pasteurella multocida*..

As with all antibiotics, appropriate *in vitro* culturing and susceptibility testing of samples taken before treatment should be conducted.

## **PHARMACOLOGY:**

**Description:** Generic amoxicillin is a semisynthetic antibiotic with a broad spectrum of activity. It provides bactericidal activity against a wide range of common gram-positive and gram-negative pathogens. Chemically, it is d(-)- $\alpha$ -amino-p-hydroxybenzyl penicillin trihydrate.

**Action:** Generic amoxicillin is stable in the presence of gastric acid and may be given without regard to meals. It is rapidly absorbed after oral administration. It diffuses readily into most body tissues and fluids with the exception of brain and spinal fluid, except when meninges are inflamed. Most of the amoxicillin is excreted unchanged in the urine.

Amoxicillin is similar to ampicillin in its bactericidal action against susceptible organisms. It acts through the inhibition of biosynthesis of cell wall mucopeptide. *In vitro* and/or *in vivo* studies have demonstrated the susceptibility of most strains of the following gram-positive and gram-negative bacteria:  $\alpha$ - and  $\beta$ - haemolytic streptococci, nonpenicillinase-producing staphylococci, *Streptococcus faecalis*, *Escherichi coli*, and *Proteus mirabilis*. Because it does not resist destruction by penicillinase, it is not effective against penicillinase-producing bacteria, particularly resistant staphylococci. All strains of *Pseudomonas* and most strains of *Klebsiella* and *Enterobacter* are resistant.

## **DOSAGE AND ADMINISTRATION:**

**Dogs:** The recommended dosage is 10 mg/lb of body weight once a day.

**Cats:** The recommended dosage is 50 mg (5-10mg/lb) once a day.

Dosage should be continued for 5-7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy.

**CONTRAINDICATIONS:** The use of this drug is contraindicated in animals with a history of an allergic reaction to penicillin.

**PRECAUTIONS:** Do not store at temperatures above 25°C (77°F).

**CAUTIONS:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**WARNINGS:** For use in dogs and cats only.

**ADVERSE REACTIONS:** Amoxicillin is a semisynthetic penicillin and has the potential for producing allergic reactions. If an allergic reaction occurs, administer epinephrine and/or steroids.

**PRESENTATION:** Generic amoxicillin is supplied in 6 strengths: 50 mg, 100 mg, 200 mg, 300 mg and 400 mg in bottles of 500 tablets; 800 mg in bottles of 250 tablets.

**MANUFACTURED BY:** Smart Drug Systems, Inc., Pawcatuck, CT 06379